

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY WASHINGTON, D.C. 20460

OFFICE OF CHEMICAL SAFETY AND POLLUTION PREVENTION

November 29, 2016

Tracy Jackson Regulatory Affairs Associate Certis USA, LLC 9145 Guilford Road Suite 175 Columbia, MD 21046

Subject: Non-PRIA (Pesticide Registration Improvement Act) Labeling Amendment – additional

optional text and deleting all alternate brand names

Product Name: Neem Oil RTU EPA Registration Number: 70051-13 Application Date: 3 November 2016 OPP Decision Number: 523329

Dear Ms. Jackson:

The amended labeling referred to above, submitted in connection with registration under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), as amended, is acceptable.

This approval does not affect any terms or conditions that were previously imposed on this registration. You continue to be subject to existing terms or conditions on your registration and any deadlines connected with them.

A stamped copy of your labeling is enclosed for your records. This labeling supersedes all previously accepted labeling. You must submit one (1) copy of the final printed labeling before you release this product for shipment with the new labeling. In accordance with 40 CFR § 152.130(c), you may distribute or sell this product under the previously approved labeling for 18 months from the date of this letter. After 18 months, you may only distribute or sell this product if it bears this new revised labeling or subsequently approved labeling. "To distribute or sell" is defined under FIFRA section 2(gg) and its implementing regulation at 40 CFR § 152.3.

Should you wish to add/retain a reference to your company's website on your label, then please be aware that the website becomes labeling under FIFRA and is subject to review by the U.S. Environmental Protection Agency (EPA). If the website is false or misleading, the product will be considered to be misbranded and sale or distribution of the product is unlawful under FIFRA section 12(a)(1)(E). 40 CFR § 156.10(a)(5) lists examples of statements the EPA may consider false or misleading. In addition, regardless of whether a website is referenced on your product's label, claims

Page 2 of 2 EPA Reg. No. 70051-13 OPP Decision No. 523329

made on the website may not substantially differ from those claims approved through the registration process. Therefore, should the EPA find or if it is brought to our attention that a website contains false or misleading statements or claims substantially differing from the EPA-approved registration, the website will be referred to the EPA's Office of Enforcement and Compliance Assurance.

Your release for shipment of this product constitutes acceptance of these terms. If these terms are not complied with, this registration will be subject to cancellation in accordance with FIFRA section 6.

If you have any questions, please contact Cody Kendrick of my team by phone at (703) 347-0468 or via email at kendrick.cody@epa.gov.

Sincerely,

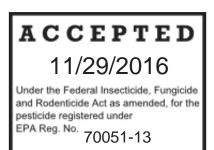
Andrew Bryceland, Team Leader Biochemical Pesticides Branch Biopesticides and Pollution Prevention Division (7511P) Office of Pesticide Programs

andrew . Buycelow

Enclosure

Neem Oil RTU

Fungicide/MITICIDE/INSECTICIDE





Revision Date: 2016-10-20

Revises: 2010-12-31 ESL

Water Based

FOR ORGANIC GARDENING

For use on roses, flowers, houseplants, ornamental trees and shrubs, fruits, nuts, and vegetables in and around the home and home garden.

Controls blackspot, powdery mildew, rust, spider mites, aphids, whiteflies, and other insect pests.

Can be Used Up to Day of Harvest

ACTIVE INGREDIENT:

Clarified Hydrophobic Extract of Neem Oil	0.9%
OTHER INGREDIENTS:	99.1%
TOTAL	100.0%

KEEP OUT OF REACH OF CHILDREN CAUTION

See inside panels for additional precautionary statements

Page **1** of **7**

- { } Symbolizes explanatory text to the reviewer
- [] Indicates optional text

(The following text may or may not appear, in whole or part, on the Front Panel of the final label:)

Referral Statements:

See [side][back][right][left][inside][other] panel for [additional] [[precautionary] [and] [first aid] statements] [[use] directions [for use]; See [attached] [booklet] [book] for [additional] [[precautionary] [and] [first aid] statements] [[use] directions [for use]]; Refer to [inside of] label booklet for [additional] [precautionary] [first aid] information [and] [[Directions] for Use] [including] [First Aid] [and] [Storage and Disposal]; Peel [back] [book] [booklet] [label] [here] [\blacktriangleright] [\rightarrow] {may be accompanied by an arrow or other indicator}

Manufactured by:

Certis USA, L.L.C.

9145 Guilford Rd. Suite 175

Columbia, Maryland 21046

EPA Reg.No. 70051-13

EPA Est. No. 70051-CA-001

Net Contents: lot Number:

Revision Date: 2016-10-20

FIRST AID

If Inhaled: Move person to fresh air. If person is not breathing, call 911 or an ambulance, then give artificial respiration, preferably by mouth-to-mouth, if possible. Call a poison control center or doctor for further treatment advice.

If in eyes: Hold eye open and rinse slowly and gently with water for 15-20 minutes. Remove contact lenses, if present, after the first 5 minutes, then continue rinsing eye. Call a poison control center or doctor for treatment advice.

If on skin or clothing: Take off contaminated clothing. Rinse skin immediately with plenty of water for 15-20 minutes. Call a poison control center or doctor for treatment advice.

Have the product container or label with you when calling a poison control center or doctor, or going for treatment. Hot Line Number: 1-800-255-3924

PRECAUTIONARY STATEMENTS

HAZARDS TO HUMANS AND DOMESTIC ANIMALS

CAUTION

Harmful if inhaled. Avoid breathing spray mist. Causes moderate eye irritation. Harmful if absorbed through skin. Avoid contact with skin, eyes, or clothing. Wash thoroughly with soap and water after handling and before eating, drinking, chewing gum, or using tobacco. Remove and wash contaminated clothing before reuse. Prolonged or frequently repeated skin contact may cause allergic reactions in some individuals.

ENVIRONEMNTAL HAZARDS

To protect the environment, do not allow pesticide to enter or run off into storm drains, drainage ditches, gutters or surface waters. Applying this product in calm weather when rain is not predicted for the next 24 hours will help to ensure that wind or rain does not blow or wash pesticide off the treatment area.

BEE HAZARD

The product is toxic to bees exposed to direct treatment. Do not apply this product while bees are actively visiting the treatment area.

Revision Date: 2016-10-20

DIRECTIONS FOR USE

IT IS A VIOLATION OF FEDERAL LAW TO USE THIS PRODUCT IN A MANNER INCONSISTENT WITH ITS LABELING.

GENERAL INFORMATION

- Three Garden Products in One
- Multi-purpose fungicide/insecticide/miticide-3 in 1 product.
- Kills eggs, larvae and adult stages of insects
- Prevents fungal attack of plant tissues.
- Not for use in food-handling areas
- Shake well before using
- Thorough plant coverage is essential to obtain optimal levels of control.
- Do not apply to wilted or otherwise stressed plants, or to newly transplanted material prior to root establishment.
- As with other pest control products, exercise care in timing applications to early morning/late evening to minimize the potential for leaf burn.
- Use with care on plants with tender tissue. Check for leaf burn in small-scale trials prior to use.

(The following text may or may not appear, in whole or part, in the Directions for Use section on the final label:)

[Optional For Use with EZ Sprayer]

EZ Connect Sprayer [Sprayer directions]

- Remove sprayer. Pull cord ALL THE WAY OUT.
- Remove top from cap on bottle.
- Insert (color) plug into spout on cap until it clicks.
- Twist nozzle on sprayer to the spray position.

Revision Date: 2016-10-20

FUNGICIDE USE

Application Instructions

- Neem Oil RTU is an effective fungicide for the prevention and control of various fungal diseases including black spot on roses, powdery mildew, downy mildew, anthracnose, rust leaf spot, botrytis, needle rust, scab, and flower, twig and tip blight.
- Neem Oil RTU may be used on all roses, flowers, houseplants, ornamental trees and shrubs, fruits, nuts, and vegetables grown in and around the home and home garden.
- As a preventative, apply Neem Oil RTU on a 7 to 14 day schedule until the potential for disease development is longer present. Spray to run off. Complete coverage of all plant tissue is necessary for control.
- To control disease already present, apply Neem Oil RTU on a 7-day schedule until disease pressure is eliminated. Then continue spraying on 14-day schedule to prevent the disease from recurring. Spray to run off. Complete coverage of all plant tissue is necessary for control.
- To prevent rust leaf spot diseases, anthracnose, and scab, begin applications at the first sign of spring budding.
- To prevent powdery mildew, apply in mid-summer or when disease is first detected. Continue applications until disease pressure no longer exists.
- To prevent black spot on roses, begin applications at first bud emergence in spring.
 Apply Neem Oil RTU on a 14-day preventative schedule through the spring and fall to prevent disease emergence.

INSECTICIDE USE

Indicates deleted text

Application Instructions

- Neem Oil RTU is an effective insecticide for the control of various insect pests including whiteflies, mealy bugs, armyworms, hornworms, leafhoppers, bagworms, leafminers, psyllids, fruit flies, loopers, budworms, beetles (Including Japanese beetles), aphids, scales, caterpillars, midges, budworms, and mites (including spider mites).
- Neem Oil RTU may be used on all roses, flowers, houseplants, ornamental trees and shrubs, fruits, nuts, and vegetables grown in and around the home and home garden.
- Apply Neem Oil RTU at first sign of insects/mites. Neem Oil RTU is most effective in controlling insects/mites when applied on a 7-14 day schedule. For heavy insect populations, apply on a 7-day schedule. Spray to run off. Complete coverage of all plant tissue is necessary for control.

Revision Date: 2016-10-20

STORAGE & DISPOSAL

<u>Pesticide Storage</u>: Keep in original container. Store away from direct sunlight, feed, or foodstuffs. Keep container tightly sealed when not in use. Keep from freezing.

Pesticide and Container Handling

If empty: Nonrefillable container. Do not reuse or refill this container. Place in trash or offer for recycling if available.

If partly filled: Call your local solid waste agency or 1-800-CLEANUP for disposal instructions. Never place unused product down any indoor or outdoor drain.

WARRANTY

Certis USA, L.L.C. warrants that the material contained herein conforms to the description on the label and is reasonably fit for the purposes referred to in the directions for use. Timing and method of application, weather, watering practices, nature of soil, the insect problem,

Page **6** of **7**

Revision Date: 2016-10-20

{	}	Symbolizes	explanatory	text to	the	reviewer
-	_					

MASTER LABEL Neem Oil RTU, EPA Reg. No. 70051-13

condition of the crop, incompatibility with other chemicals not specifically recommended, and other influencing factors in the use of this product are beyond the control of the seller. Buyer assumes all risks of use, storage or handling of this material not strict accordance with directions given herein. NO OTHER EXPRESS OR IMPLIED WARRANTY OF THE FITNESS OR MERCHANTABILITY IS MADE.

Revision Date: 2016-10-20